K080758

Special 510(k) Summary of Safety and Effectiveness: Modifications to the AVS™ PL PEEK Spacer System

MAR 27 2008

Proprietary Name:	AVS™ PL PEEK Spacer System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II Interevertebral body fusion device 21 CFR 888.3080
Device Product Code:	MAX
For Information contact:	Vikki M. O'Connor Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8206 Fax: (201) 760-8345 Email: Vikki.O'Connor@Stryker.com
Date Summary Prepared:	March 13, 2008
Predicate Device	AVS PL PEEK Spacer, K073470 DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System: P960025 (i.e., Brantigan Cage)
Predicate Device Information	The subject AVS PL PEEK Spacers and the predicates AVS PL PEEK Spacers and DePuy's Lumbar I/F Cage (i.e., Brantigan Cage) share similar design features: • Rectangular angled shape • Lateral fenestrations • Serrations on the superior and inferior surfaces

- Comparable heights, widths, and angles
- Materials and mechanical testing results are similar between the subject device and the listed predicates.

Description of Device Modification

This Special 510(k) premarket notification is intended to introduce the following design changes to the 0° AVS™ PL PEEK Spacers: The ogival shaped nose of the implant has been changed to a tapered design to facilitate insertion. The threaded hole on the front side of the implant has been omitted as it is not needed to remove the implant and field feedback confirms it would likely not be used. In the smaller heights, the back sided threaded hole has been adapted to remain consistent with the existing instruments (i.e., the two Inserters), and the back side of the spacer has been tapered in the frontal plane to match the geometry of the vertebral endplates and the two flat surfaces have been increased to improve connection with the Inserters. Note that the AVS PL PEEK Spacers are also referred to as AVS Plus.

Intended Use

The Stryker Spine AVS PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS PL PEEK Spacers are to be implanted via posterior approach.

	The AVS PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).
Summary of the Technological Characteristics	Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS PL PEEK Spacers and demonstrated substantially equivalent performance characteristics to the identified predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2008

Stryker Corporation
% Ms. Vikki M. O'Connor
2 Pearl Court
Allendale, NJ 07401

Re: K080758
Trade/Device Name: AVS™ PL PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: March 17, 2008
Received: March 18, 2008

Dear Ms. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K_____

Device Name: Stryker Spine AVS PL PEEK Spacers

Indications For Use:

The Stryker Spine AVS PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS PL PEEK Spacers are to be implanted via posterior approach.

The AVS PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonetta D.

for **(Division Sign-Off)**
Division of General, Restorative, and Neurological Devices

510(k) Number K080758